

## WHAT IS CLAIMED IS:

1. A method of manufacturing a molded microneedle array comprising:  
providing a negative mold insert characterized by a negative image of microneedle  
topography wherein at least one negative image of a microneedle is characterized by an  
aspect ratio of between about 2 to 1 and about 5 to 1;  
transferring the negative mold insert into an injection molding apparatus, wherein  
the negative mold insert is exposed and defines a structured surface of a negative mold  
cavity;  
heating the negative mold cavity to a temperature above the softening temperature  
of a moldable plastic material;  
heating the moldable plastic material to at least the molten temperature of the  
moldable plastic material in a chamber separate from the negative mold cavity;  
injecting the molten plastic material into the heated negative mold cavity,  
allowing the molten plastic material to fill at least about 90 percent of the volume  
of the negative indentations defined by the negative mold insert;  
cooling the molten plastic material to a temperature below the softening  
temperature of the moldable plastic material; and  
detaching the molded microneedle array from the negative mold insert.
2. A method of manufacturing a molded microneedle array comprising:  
providing a negative mold insert characterized by a negative image of microneedle  
topography wherein at least one negative image of a microneedle is characterized by an  
aspect ratio of between about 2 to 1 and about 5 to 1;  
transferring the negative mold insert into an injection molding apparatus, wherein  
the negative mold insert is exposed and defines a structured surface of a negative mold  
cavity;  
heating the negative mold cavity to a temperature of more than about 10 degrees  
centigrade above the softening temperature of a moldable plastic material;  
heating the moldable plastic material to at least the molten temperature of the  
moldable plastic material in a chamber separate from the negative mold cavity;

injecting the molten plastic material into the heated negative mold cavity,  
allowing the molten plastic material to fill at least about 90 percent of the volume  
of the negative indentations defined by the negative mold insert;  
cooling the molten plastic material to a temperature at least below the softening  
5 temperature of the moldable plastic material; and  
detaching the molded microneedle array from the negative mold insert.

3. A method according to any one of claims 1 or 2, wherein the negative mold insert  
is formed by:

10 providing a positive mold master member characterized by microneedle  
topography wherein at least one microneedle is characterized by an aspect ratio of between  
about 2 to 1 and about 5 to 1;  
electroforming a negative mold insert around the positive mold master; and  
detaching the negative mold insert from the positive mold master member.

15 4. A method according to claim 3, wherein the positive mold master member  
comprises copper.

5. A method according to any one of claims 1 to 4, wherein the negative mold insert  
20 is fabricated by nickel electroforming.

6. A method according to any one of claims 3 to 5, wherein the microneedle  
topography of the positive mold master member is prepared by diamond turning.

25 7. A method according to any one of claims 1 to 6, wherein the microneedle array  
comprises a plurality of microneedles each having a flat tip comprising a surface area  
measured in a plane aligned with the base of about 20 square micrometers or more and 100  
square micrometers or less.

30 8. A method according to any one of claims 1 to 7, wherein the microneedle array is

formed as part of a larger array, wherein at least a portion of the larger array comprises a non-patterned substrate.

5 9. A method according to claim 8, wherein the non-patterned substrate has an area of more than about 0.10 square inch (0.65 cm<sup>2</sup>) to less than about 1 square inch (6.5 cm<sup>2</sup>).

10 10. A method according to any one of claims 1 to 9, wherein the microneedle array comprises a plurality of molded microneedles having a height greater than about 90 percent of the corresponding height of the microneedle topography in the negative mold insert.

11. A method according to claim 10, wherein the microneedle array comprises a plurality of molded microneedles having a height greater than about 95 percent of the corresponding height of the microneedle topography in the negative mold insert.

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12. A method according to any one of claims 1 to 11, wherein the moldable plastic material comprises a material selected from the group consisting of polycarbonate, polystyrene, polyethylene, polypropylene, and blends thereof.

20 13. A method according to claim 12, wherein the moldable plastic material comprises polycarbonate.

25 14. A method according to any one of claims 2 to 13, wherein the negative mold cavity is heated to a temperature of more than about 20 degrees centigrade above the softening temperature of the moldable plastic material.

15. A method according to claim 14, wherein the negative mold cavity is heated to a temperature of more than about 30 degrees centigrade above the softening temperature of the moldable plastic material.

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16. A method according to any one of claims 1 to 15, wherein the microneedle array comprises a plurality of microneedles having a pyramidal shape.

17. A method according to any one of claims 1 to 16, wherein the molten plastic material is injected into the heated negative mold cavity with a velocity of less than 2.0 in/sec (5.08 cm/sec).

18. A method according to any one of claims 1 to 17, wherein after injection of the molten material, it is held at a packed pressure of more than about 6000 psi (40.8 Mpa).

19. A method of manufacturing a negative mold insert used for preparing molded microneedle arrays comprising:

providing a positive mold master member characterized by microneedle topography wherein at least one microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1;

electroforming a negative mold insert around the positive mold master; and  
detaching the negative mold insert from the positive mold master member.

20. A method according to claim 19, wherein the positive mold master member comprises copper.

21. A method according to any one of claims 19 to 20, wherein the negative mold insert is fabricated by nickel electroforming.

22. A method according to any one of claims 19 to 21, wherein the microneedle topography of the positive mold master member is prepared by diamond turning.

23. A method according to any one of claims 19 to 22, wherein the positive mold master comprises a plurality of microneedles each having a flat tip comprising a surface area measured in a plane aligned with the base of about 20 square micrometers or more and 100 square micrometers or less.

24. A method according to any one of claims 19 to 23, wherein at least a portion of the negative mold insert comprises a non-patterned substrate.

25. A method according to claim 24, wherein the non-patterned substrate has an area of more than about 0.10 square inch (0.65 cm<sup>2</sup>) to less than about 1 square inch (6.5 cm<sup>2</sup>).

26. A method of manufacturing a molded microneedle array comprising:  
providing a negative mold insert prepared according to any one of claims 19 to 25,  
transferring the negative mold insert into a molding apparatus, wherein the  
negative mold insert is exposed and defines a structured surface of a negative mold cavity;  
providing a heated plastic material into the negative mold cavity,  
allowing the heated plastic material to fill at least about 90 percent of the volume  
of the negative indentations defined by the negative mold insert;  
cooling the plastic material to a temperature at least below the softening  
temperature of the plastic material; and  
detaching the molded microneedle array from the negative mold insert.

27. A method according to claim 26, wherein the molding apparatus is an injection molding apparatus.

28. A method according to any one of claims 26 or 27, wherein the negative mold cavity is heated to a temperature of more than about 10 degrees centigrade above the softening temperature of the plastic material prior to providing the heated plastic material to the negative mold.

29. A product manufactured according to the process of any one of claims 1 to 28.

30. A product according to claim 29, wherein the product is a drug delivery device.